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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/614,790	07/12/00	KLEYNE	S HME/7982.001

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EXAMINER

WILLIS, M

ART UNIT	PAPER NUMBER
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1619

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DATE MAILED:

02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/614,790

Applicant(s)

KLEYNE, SHARON F.

Examiner

Michael Willis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/19/00.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17:2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. Claims 1-23 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. In claim 1, the term "controllably" renders the claim vague and indefinite. The term is not defined in the specification so that the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.
5. In claim 11, the phrase "fluid has administered has" renders the claim unclear. The rejection can be overcome by removal of the first "has".
6. Claims 15 and 19 are vague and unclear due to the phrase "within about 10 seconds." The starting and stopping points for the time measurement are not clear and are not defined in the specification.
7. Claims 21 and 22 are indefinite and confusing because the size ranges of "between 10 and 50 microns" and "between about 15 and 30 microns" respectively are not within the size range of "between 50 and 150 microns" as recited in claim 20 from which both claims 21 and 22 depend.

8. Claims 2-14, 16-18, and 20-22 are rejected as being dependent on indefinite base claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. Claims 1-10 and 15-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Rocca et al (WO 96/00050) in view of Records, "The Tear Film," Chapter 3 of Volume 2 of Biomedical Foundations of Ophthalmology, Ed. William Tasman and Edward Jaeger, Lippincott Publishers.

11. Rocca et al teach an ocular treatment device and methods for applying a treatment liquid to the eye. The invention provides for the discharge of treatment liquid in a jet or multiple droplets of greater than 20 micron diameter up to 200 micron diameter to the target area of the eye (see page 1, lines 13-31 and page 8, lines 16-24). According to the specification of the instant application, the volume of the normal aqueous layer is 2 to 5 microliters (see page 1, line 30 of specification). While the volume of the normal tear film is not defined in the specification or claim 4 of the instant application, it is the position of the examiner that the volume of the normal tear film is in the range of 7-100 microliters as evidenced by R. E. Records, page 1, last complete

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paragraph. Using the formula $V = \frac{4}{3} \pi r^3$, the volume of a 200 micron diameter droplet is about 3 nanoliters. Therefore, droplets between 20 and 150 microns in diameter are in the range of 0.1-1% of the volume of the normal tear volume. Rocca et al disclose administering 5 microliters of an aqueous solution of pilocarpine hydrochloride with a flow rate of 100 microliters/second to the eye of a test subject (see page 13, lines 11-30).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocca et al (WO 96/00050) and further in view of Varma (U.S. Pat. 5,032,392).

14. Rocca et al, as applied to claims 1-10 and 15-22 above, teach an ocular treatment device and methods for applying a treatment liquid to the eye. Rocca et al disclose administering 5 microliters of an aqueous solution of pilocarpine hydrochloride with a flow rate of 100 microliters/second to the eye of a test subject (see page 13, lines 11-30). Droplet size is disclosed as around 20 microns (see page 1, lines 13-31). The reference lacks disclosure of the pH or osmolarity of the applied solutions.

15. Varma discloses aqueous ophthalmic solutions for the treatment of dryness of the eyes. Varma teaches that buffering and/or tonicity imparting agents provide

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solutions that may be applied with no discomfort and with maintenance of an osmotic balance similar to that of the natural tear film (see col. 3, line 65 through col. 4, line 2).

The most preferred osmolarities according to Varma are 300 ± 10 mOsm (see col. 4, lines 3-10). Varma also teaches that preferred solutions have a pH within the range of from ^{about} 6.6 to about 7.8 (see col. 4, lines 29-39). The reference lacks disclosure of methods of applying the solutions to the eye.

16. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the method and apparatus as taught by Rocca to include solutions with osmolarity less than 311 mOsm and pH about 6.5 in order to administer solutions with no discomfort and to maintain an osmotic balance similar to that of the natural tear film.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Embleton et al (WO 97/23177), Gonda et al (U.S. Pat. 6,070,575), Cohen et al (U.S. Pat. 5,881,956), and Laibovitz et al (U.S. Pat. 6,159,188)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers

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for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

MAW
February 9, 2001.



DANA DUDASH
SUPERVISORY PATENT EXAMINER
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